



HHS ASPR BARD A

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY

BARDA Strategic Plan 2022–2026



Fortifying the Nation's Health Security

May 2022



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Preface from the BARDA Director

As the Biomedical Advanced Research and Development Authority enters its 16th year, we are releasing a new Strategic Plan focused on strengthening the health security of the nation, embracing lessons learned from the COVID-19 pandemic, incorporating new avenues of promising research and development, and addressing the imperative for medical countermeasures that are safe, effective, and widely accessible to all Americans. BARDA understands the importance of delivering lifesaving medical countermeasures quickly, which requires a sustainable, mission-ready response posture with a workforce of scientists and other experts who can readily adapt to protect Americans from emerging threats. This blueprint creates a framework on which the nation's preparedness and response is strengthened by a world-class workforce and diverse public-private partnerships.

Although the COVID-19 pandemic spotlighted both new and known challenges in the nation's pandemic preparedness and response strategy, the intrinsic flexibility of BARDA's comprehensive partnership model and portfolio approach allowed a rapid pivot and acceleration in the development of vaccines, diagnostics, and therapeutics against COVID-19. These investments also helped to improve the manufacturing and fill-finish capacity for seasonal influenza vaccines, demonstrating that sustained investment in the pandemic influenza strategy will equip BARDA with the ability to rapidly respond to emerging and reemerging pandemic pathogens. In addition to supporting nearly [100 products as part of the COVID-19 portfolio](#), BARDA has supported [62 U.S. Food and Drug Administration approvals, licensures or clearances](#), four products used to halt Ebola outbreaks in western Africa, and more than 18 products in development for antibiotic resistance, one of the top global health threats.

This plan sets out how BARDA will continue to work with our partners to further secure the nation during public health emergencies including expanding the domestic supply chain for production of sterile injectables. The COVID-19 pandemic has highlighted that new and innovative approaches are required to appropriately respond during a large-scale public health emergency. BARDA will emphasize innovation across all sectors of our portfolio. BARDA has established an ecosystem of innovation to include CARB-X, BARDA Ventures, an Accelerator Network, and the Blue Knight program.

Consistent with the American Pandemic Preparedness Plan and other policies, BARDA scientists, technical experts, and contracting professionals leverage unique authorities granted by Congress to promote innovation, support advanced research and development, and facilitate procurement of medical countermeasures. Effectively preparing for future pandemics and other health security threats, we must embrace ideas and creativity from private-sector partners both large and small so that the resulting medical countermeasures serve the needs of the diverse populations we serve. Building and supporting a more inclusive, diverse workforce further enhances this capability and capacity and enables BARDA's decision-making to reflect a broader and deeper understanding of real-world application of medical countermeasures.

BARDA will fortify the nation's health security with our partners, stakeholders, and workforce. This Strategic Plan establishes how this will be achieved in BARDA's next five years.

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Introduction

Within the Assistant Secretary for Preparedness and Response (ASPR), BARDA was established and mandated by Congress as the organization within the U.S. Government to catalyze innovation in advanced research and development, manufacturing, and procurement of medical countermeasures (MCMs).¹ These lifesaving MCMs are needed to protect people during public health emergencies from threats such as chemical, biological, radiological, and nuclear (CBRN) incidents (whether accidental or intentional), pandemic influenza, COVID-19, and other emerging infectious diseases. BARDA works closely with interagency partners through the [Public Health Emergency Medical Countermeasures Enterprise \(PHEMCE\)](#) to ensure a coordinated, whole-of-government approach to MCM preparedness and response.²

The BARDA model has proven successful in leveraging public-private partnerships to accelerate development of MCMs that are vital to national security. BARDA helps its partners promote innovation and develop countermeasures from early research through FDA licensure and clinical application. Over the last 15 years, BARDA has supported [62 FDA approvals, licensures, and clearances of MCMs](#).

The COVID-19 pandemic serves as a stark reminder of the need to protect individuals from public health emergencies. BARDA was critical in the development, manufacturing, and procurement of MCMs that saved countless lives during the pandemic – the direct result of the hard work and dedication of BARDA’s workforce, stakeholders, and industry partners. These efforts made what might have seemed impossible at the onset of the pandemic a reality. However, as the COVID-19 pandemic continues to pose additional challenges and as the U.S. and the globe will begin to recover from the pandemic’s impact, BARDA now faces a crucial inflection point. While BARDA continues its work countering the COVID-19 pandemic, it must continue to build its capacities and capabilities, prepare for new and emerging threats with flexible countermeasures and partnerships, and build the workforce needed to help BARDA achieve success for the next five years and beyond.

BARDA’s Strategic Plan to fortify the nation’s health security is built upon four strategic goals. First, BARDA will enhance preparedness against health security threats; investing in innovative technologies that will enhance our portfolio of MCMs. Second, BARDA will strengthen its response posture to improve our capacity to support public health emergency response efforts. Third, BARDA will develop and nur-



Figure 1: The BARDA Model

- 1 MCMs include both pharmaceutical interventions (e.g., vaccines, antimicrobials, antidotes, and antitoxins) and non-pharmaceutical interventions (e.g., ventilators, diagnostics, personal protective equipment, and patient decontamination) that are used to prevent, mitigate, or treat the adverse health effects of a deliberate, unintentional, or naturally occurring public health emergency.
- 2 PHEMCE members include ASPR, ASPR/BARDA, ASPR/Strategic National Stockpile (SNS), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH) (including the National Institute of Allergy and Infectious Diseases), and Food and Drug Administration (FDA), Department of Defense (DoD), Department of Veterans Affairs, Department of Homeland Security, and Department of Agriculture.

BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY

VISION

Fortifying the nation's health security to rapidly respond to public health emergencies with MCMs that save lives

MISSION

Improve preparedness and response through public-private partnerships that advance research and development, manufacturing, and procurement of MCMs that protect against health security threats such as chemical, biological, radiological, and nuclear (CBRN) incidents, pandemic influenza, COVID-19, and other emerging infectious diseases



VALUES

- **Leadership:** We are recognized leaders in the USG for MCM innovation, advanced development, and manufacturing.
- **Service:** We have a dedicated team of subject matter experts to assist our partners in the development of MCMs.
- **Collaboration:** We work as a mission-oriented team within BARDA and with interagency and private sector partners to develop and implement the best solutions.
- **Adaptability:** We readily identify, adapt, and apply the best tools in our arsenal to protect Americans from emerging threats under deep uncertainty.
- **Diversity:** We represent and meet the needs of the diverse populations we serve.
- **Integrity:** We make decisions based on science and the national interest to protect the public from health security threats.

ture partnerships with the private sector to advance the best MCM solutions to mitigate health security threats. Finally, BARDA will ensure it expands, maintains, and supports a world-class workforce to serve our country's critical needs.

BARDA's Five-Year Strategic Plan

This strategic plan is built on four strategic goals to fortify and strengthen BARDA:

1. Enhancing **PREPAREDNESS** by investing in development of a robust pipeline of innovative MCMs
2. Embracing our role as an agile **RESPONSE** organization
3. Expanding and sustaining public-private **PARTNERSHIPS**
4. Continuing to invest in the organization's **WORKFORCE**.

Each goal is supported by objectives that are critical to achieving the goal. Each objective identifies new activities and associated key milestones to achieve by 2026. Each of these milestones are ambitious targets that may be challenging to achieve. But when they are interwoven together, BARDA will be able to continually provide a solid foundation that protects our nation's health security.

Activities and milestones in this plan may be contingent upon additional legislative authorities and budgetary resources beyond those currently available. However, the price of pursuing these activities is small compared to the cost and consequences of waiting to respond to health security threats after they occur.

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Goal 1: Preparedness

Rapidly develop safe, effective medical countermeasures accessible to all Americans



Since its creation in 2006 through the Pandemic and All-Hazards Preparedness Act (Public Law No. 109-417), BARDA has steadily grown its capacity to develop life-saving MCMs to protect Americans from public health emergencies. Whether protecting against known national security threats such as anthrax or newly emerging infectious diseases like COVID-19, BARDA has successfully partnered with the private sector to overcome economic and scientific challenges to develop lifesaving MCMs available when needed during public health emergencies. BARDA will continue to support advanced development and procurement of MCMs for known high-priority threats and will leverage lessons learned and innovative technologies to enhance preparedness against potential known and unknown threats. It will focus investments on technologies that have the potential to make available MCMs faster, safer, and more accessible. It will achieve this goal by: (1) developing MCMs that address known threats and are rapidly adaptable to be applied against new threats, (2) spurring innovation in MCM development, (3) understanding and addressing needs of end-users who administer MCMs, and (4) developing MCMs to meet the needs of the entire population.



Objective 1.1: Accelerate the development of agile MCMs that can pivot and be brought to scale in response to new threats

BARDA fulfills a critical role in protecting Americans from health security threats by developing MCMs that can be readily adapted and deployed in public health emergencies. However, since it is not possible to know exactly what threat will be realized in the next public health emergency, BARDA invests in a portfolio of proven technologies that are flexible and can address a multitude of threats. These proven technologies are MCMs: (1) built on versatile platforms that can be rapidly adapted to address a new threat and (2) licensed, approved, or cleared for another indication, helping sustain their availability for future public health emergency response.

Early in the COVID-19 response, BARDA evaluated vaccine and therapeutic partnerships to identify proven technologies that could be quickly adapted to develop products against SARS-CoV-2, the virus that causes COVID-19. For example, BARDA supported a proven technology to discover, develop, and produce optimized, fully human antibodies against Ebola virus, which provided the basis for a therapeutic addressing COVID-19. This partnership led to the first Ebola treatment licensed by the U.S. Food and Drug Administration (FDA), and the same technology was leveraged for a therapeutic targeting SARS-CoV-2. In addition, BARDA investments in an mRNA-based vaccine against the previously emerging Zika virus helped develop the mRNA technology platform that was rapidly applied to create a vaccine against SARS-CoV-2. The flexibility and rapid scalability of these technology investments proved invaluable in the fight against COVID-19.

WHAT'S NEW?



BARDA will launch new efforts to address emerging infectious diseases and prioritize expansion of efforts to develop proven technologies for vaccines, therapeutics, and diagnostics that can be readily adapted for new threats.



OBJECTIVE 1.1 KEY MILESTONES

- Establish a new Emerging Infectious Diseases Division, which will pursue technologies that can be readily adapted and used against a range of threats and support efforts under the American Pandemic Preparedness Plan, if and when the Plan is appropriately funded.³
- Support advanced development and approval of therapeutics, including:
 - Achieving FDA approval for two novel, oral antivirals ready for stockpiling. Support will focus on direct-acting antivirals with substantial reduction in morbidity and mortality from outbreak-prone virus families,
 - Establishing an antiviral repurposing program, aimed at evaluating approved or late-stage antivirals for efficacy against related pathogens of interest,
 - Establishing a threat-agnostic program that focuses on broad-acting therapeutics, either host or pathogen directed, that interfere with common mechanisms of pathogen infection, replication, transmission, pathogenesis, etc., and that are capable of preventing and/or treating infections across pathogen families, and
 - Achieving FDA approval of two threat-agnostic and host-directed therapeutics for severe disease by targeting potential organ damage (e.g., acute lung injury, endothelial injury).
- Support advanced development and FDA approval of vaccines leveraging proven technologies, including:
 - Investing in at least five different vaccine platforms across the array of virus families with pandemic potential,
 - Developing at least one prototype vaccine candidate for each virus family with pandemic potential, and
 - Evaluating each prototype vaccine candidate in nonclinical studies, clinical studies, and scale-up of manufacturing; validating commercial scale manufacturing and generating sufficient material ready to use for outbreak responses.
- Support advanced development and approval of pathogen-agnostic, pathogen-specific, and host-directed diagnostics across the spectrum of potential threats, including:
 - Evaluating laboratory and point-of-care testing that leverages existing platforms and can be rapidly adapted to emerging threats,
 - Accelerating emerging technologies that move testing closer to the patient and facilitate testing in limited healthcare resource settings, and
 - Achieving regulatory clearance of one test on at least two separate home use molecular diagnostic testing platforms.

³ American Pandemic Preparedness: Transforming Our Capabilities, September 2021. Available at: <https://www.whitehouse.gov/wp-content/uploads/2021/09/American-Pandemic-Preparedness-Transforming-Our-Capabilities-Final-For-Web.pdf>



Objective 1.2: Catalyze innovation across the MCM development pipeline

BARDA will continue to work with innovators to develop cutting-edge technologies that can save lives during an emergency. In 2016, BARDA launched the [Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator \(CARB-X\)](#) program to reinvigorate the preclinical pipeline of novel drugs, vaccines, and diagnostics to address antibacterial resistance. CARB-X provides start-ups and biotech companies support to develop innovative preclinical candidates and position these candidates for continued clinical development under BARDA's Advanced Research and Development (ARD) program, another ARD funder (e.g., AMR Action Fund), or a large pharmaceutical company. In 2018, BARDA established the [Division of Research, Innovation, and Ventures \(DRIVE\)](#) to identify and de-risk the world's most promising technologies and capabilities, no matter their origin. DRIVE's Easy Broad Agency Announcement (EZ-BAA) has enabled innovation through a novel acquisition vehicle used to award contracts to product developers targeting a 30-day review period (with some awarded in as few as nine days). The EZ-BAA was used in early 2020 to rapidly engage companies with promising COVID-19 products accelerating the availability of many of the COVID-19 diagnostics in the early months of the pandemic. In 2019, BARDA co-launched the [Blue Knight](#) initiative to engage with entrepreneurs, investors, and thought leaders throughout the world to identify opportunities for MCM innovation.

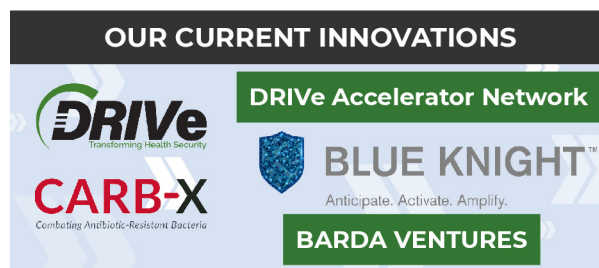


Figure 2: Current Innovation Programs



OBJECTIVE 1.2 KEY MILESTONES

- Expand commitment to combat antimicrobial resistance through:
 - Establishment of the follow-on to the CARB-X program and continue support of the CARB Accelerator resulting in the transition of at least two antibacterial candidates from the Accelerator into the BARDA advanced research and development portfolio,
 - FDA approval of at least three novel antibacterials,
 - Procurement of approved novel antibacterials through Project BioShield, and
 - Development of at least one new diagnostic to inform appropriate antibiotic use.
- Invest in and advance commercialization of up to three digital-based MCMs (e.g., software as a medical device, digital diagnostics, digital epidemiology tools).
- Develop an organ-on-a-chip platform to promote the development and future approval of innovative treatments for chemical exposure.
- Establish a multi-tissue microphysiological platform for rapid assessment of MCM effectiveness.
- Expand the Accelerator Network to capture early-stage innovation across the world and in underserved regions to promote pandemic preparedness.



- Transition at least five Blue Knight and/or Accelerator Network technologies beyond early-stage development to commercialization.
- BARDA Ventures will, through that fund, establish a portfolio of 20 to 25 companies with high-priority technologies.
- Accelerate the availability and regulatory compliance of threat-agnostic laboratory diagnostic tests for use in the early weeks of an emerging disease outbreak.
- Expand use of the EZ-BAA award mechanism across BARDA to enhance support for innovative early-stage developers in all areas of interest across the agency.

Objective 1.3: Embrace end-user needs and promote interventions across the continuum of care

BARDA leverages knowledge on how MCMs are used by health care providers and seeks opportunities to improve patient outcomes by intervening earlier in disease or injury progression, potentially mitigating more severe outcomes.⁴ Promoting access to MCM interventions in and near communities where patients live and in their homes can reduce the burden on health care delivery systems during a public health emergency.

BARDA seeks to understand operational challenges that users may face when administering an MCM, whether the end user is a physician, nurse, emergency medical technician, family member, or the patient themselves. BARDA has engaged with patients, health care providers, and professional societies to foster a better understanding of end user needs and identify solutions to operational challenges. For example, BARDA engaged with the American Burn Association and American College of Surgeons in developing thermal burn MCMs, the Radiation Injury Treatment Network in developing acute radiation syndrome MCMs, and the Sepsis Alliance and END Sepsis foundations to develop tools to fight sepsis. In addition, BARDA's Primary Response Incident Scene Management (PRISM) chemical decontamination guidance was informed by extensive input from first responders and serves as the standard protocol for chemical decontamination. The engagements also helped development of MCMs – including non-pharmaceutical interventions – that directly address gaps that practitioners identified.

OBJECTIVE 1.3 KEY MILESTONES

- Expand engagement with professional societies, foundations, practitioners, state, local, tribal, and territorial stakeholders, and patients to ensure solutions fulfill unmet needs, including those for routine health care. Key areas in which BARDA will seek input from these stakeholders to inform MCM development include:
 - Treating trauma and radiation injuries (including next-generation blood products) from nuclear threats,

WHAT'S NEW?



BARDA will develop MCMs that enhance response capabilities and reduce burden on the health care system by promoting new engagements with end users to identify potential technologies at key inflection points along the continuum of care. This will better position BARDA to respond to future threats.

⁴ Continuum of Care Definition: "In medicine, describes the delivery of health care over a period of time. In patients with a disease, this covers all phases of illness from diagnosis to the end of life." <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/continuum-of-care>

- Repurposing commonly used MCMs to address chemical threats,
- Providing point-of-use/at-home infection detection and health monitoring tools, and
- Developing broad-acting, threat-agnostic MCMs effective across families of bacterial and viral pathogens.
- Support the development and commercialization of alternative delivery technologies that will reduce the need for cold chain distribution and manufacturing of needles and syringes, with the goal of having at least one alternative vaccine delivery product FDA-approved and integrated into a vaccine.
- Expand engagement with international stakeholders to ensure alignment on needs in the emerging infectious disease mission space.

Objective 1.4: Protect all members of our communities against an evolving threat landscape

One of the critical lessons of the COVID-19 pandemic is the disproportionate impact of a public health emergency on underserved and at-risk populations.⁵ Driving factors of these disparities included: race, ethnicity, age, gender, comorbidities, geographical region, and socioeconomic status. Identifying ways to address inequities associated with these social determinants of health is an important aspect of BARDA's mission.

Lifesaving MCMs developed by BARDA must be accessible to all Americans who may benefit from them.

BARDA includes consideration of at-risk population needs in MCM development. For example, BARDA supported the development of a cell-based inactivated influenza vaccine approved for use in persons six months of age and older. BARDA supported approval of a smallpox vaccine that could be used during an emergency in immunocompromised individuals (e.g., individuals with HIV or atopic dermatitis). BARDA also supported the licensure of the first therapeutic for Zaire ebolavirus in adults and pediatric patients, including neonates born to a mother who is RT-PCR positive for Zaire ebolavirus. BARDA is currently supporting the development of antibacterial MCMs for pediatric patients.

WHAT'S NEW?



BARDA will further address the needs of at-risk populations and pursue approaches to design and perform clinical trials that promote wider participation and represent all population segments.

OBJECTIVE 1.4 KEY MILESTONES

- Establish and implement a plan for expanding the use of MCMs to pediatric populations.
- Design and pre-position adaptive clinical trials, platform trials, and master protocols when appropriate for testing MCMs in multiple subpopulations across a range of threat agents.
- Focus on development of low-cost, high performance MCMs, such as diagnostics and digital public health guidance tools, that can be used in low-acuity and limited healthcare resource settings, such as health centers and tribal facilities, nursing homes, physician's offices, temporary testing centers, and homes.

⁵ <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/racial-ethnic-disparities/index.html>





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Goal 2: Response

Enhance and maintain a sustainable, mission-ready response posture

Since its inception, BARDA has been mobilized to respond to the H1N1 influenza virus, Zika virus, Ebola virus (multiple times), and SARS-CoV-2 public health emergencies, as well as prepared to respond to influenza virus outbreaks such as H5N1 and H7N9. These experiences underscore the importance of mobilizing quickly, leveraging partnerships, and identifying proven technologies that can be rapidly adapted to new threats. BARDA will achieve this goal by: (1) evaluating the response posture for MCMs in BARDA's portfolio, (2) ensuring manufacturing capabilities can meet the scale needed during emergencies, (3) providing support services to industry during an emergency, (4) pursuing acquisition vehicles that can be rapidly leveraged in an emergency, and (5) addressing all segments of the population in BARDA's response posture.



Explore BARDA's Pandemic Preparedness Principles

BARDA has identified six key preparedness principles that enable a robust response to Emerging Infectious Diseases.

Pandemic
Influenza
Preparedness



Emerging
Infectious Diseases
Preparedness

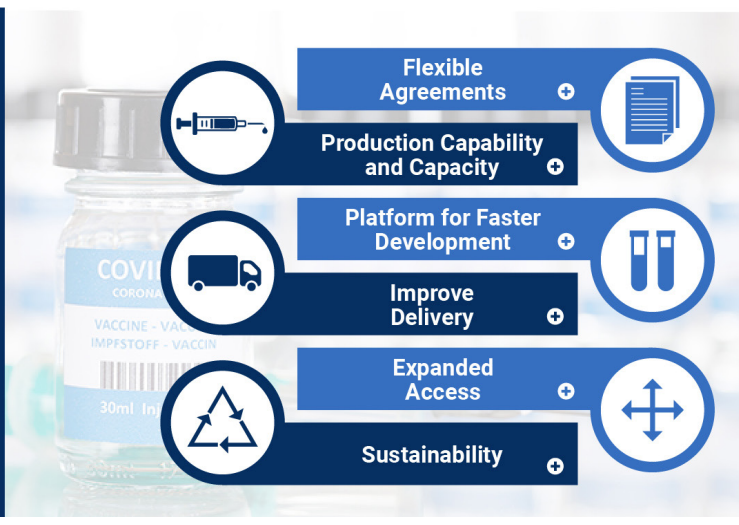


Figure 3: BARDA's Pandemic Preparedness Principles

Objective 2.1: Enhance BARDA's response posture by leveraging a diverse MCM portfolio of proven technologies

Responding to an emerging infectious disease or CBRN threat requires more than having a product stockpiled. When a new threat emerges, BARDA immediately assesses its portfolio to identify MCMs that could be used to respond. While BARDA's portfolio includes a diversified pipeline of products, not all threats can be identified before an emergency, and not all MCMs can be scaled and fielded effectively to fully mitigate the new threat. BARDA has activated its Incident Management Team (IMT) to support response efforts to several public health emergencies, such as H1N1 influenza virus, Zika virus, Ebola virus, and SARS-CoV-2.

BARDA will continue to identify opportunities for product development to address gaps in preparedness, working closely with the PHEMCE partner agencies. A critical aspect of these interagency collaborations are portfolio exchanges that ensure coordination among partners.





WHAT'S NEW?

BARDA will assess its readiness to meet the needs of a public health emergency and identify opportunities to leverage technology innovation to address gaps through additional product development.

Pandemic influenza has been recognized by the PHEMCE as a high-priority threat to address with MCMs. The 2005 HHS Pandemic Influenza Plan⁶ and the 2006 National Strategy for Pandemic Implementation Plan⁷ specified the establishment of pre-pandemic vaccine stockpiles sufficient to protect front-line personnel and at-risk populations, including military personnel. To this end, BARDA manages the U.S. National Pre-Pandemic Influenza Vaccine Stockpile (NPIVS) to

address this threat. BARDA has maintained continuous partnerships with all FDA-licensed influenza vaccine manufacturers since 2005 to maintain and strengthen pandemic readiness. This enables the NPIVS program to manage and continuously update a pre-pandemic influenza vaccine stockpile comprised of pre-pandemic bulk antigens determined to pose a significant risk for a pandemic. In addition, it sustains adjuvant stockpiles that permit antigen-sparing approaches, and it allows for rapid commercial-scale response capability, increasing the number of people who can be administered an adjuvanted vaccine. The NPIVS also assesses the safety and immunogenicity of various pre-pandemic influenza virus vaccines as well as the dose-sparing capacity of stockpiled adjuvants in clinical trials to inform strategic options in mitigating an emerging influenza pandemic.

OBJECTIVE 2.1 KEY MILESTONES

- Evaluate how BARDA's MCM portfolio can be used in response to identified threats, and address gaps. This team will evaluate partners, proven technologies, and U.S. manufacturing capacity and capabilities to ensure they are maintaining readiness to be rapidly scaled up in a response.
- Complete an evaluation of BARDA-supported products in the Strategic National Stockpile (SNS). Key areas of emphasis will include:
 - Assessments of the costs and benefits of developing next-generation products that may improve upon existing MCMs, including consideration of development time, cost, efficacy, safety, ease of use, and scalability of manufacturing, and
 - Assessments of the current indication of products to inform operational gaps in terms of target population, boosting strategies, cold-chain logistics, and other aspects related to the target product profile.
- Revitalize the armamentarium of antibiotics that could be stockpiled to address antimicrobial resistant threats that could complicate any public health emergency.

6 <https://www.cdc.gov/flu/pdf/professionals/hhspandemicinfluenzaplan.pdf>

7 <https://www.cdc.gov/flu/pandemic-resources/pdf/pandemic-influenza-implementation.pdf>

Objective 2.2: Build a resilient, surge-capable, flexible manufacturing ecosystem that prioritizes increased domestic capacity

Developing a proven technology that can be readily adapted to a newly emerging threat works only if it can be manufactured rapidly at commercial scale to meet the emergency need. The 2010 PHEMCE Review⁸ highlighted the lack of rapid domestic manufacturing for a pandemic response. Since 2012, HHS has invested in the Centers for Innovation in Advance Development and Manufacturing (CIADM). The CIADMs have promoted U.S.-based manufacturing capacity for public health emergencies, including retrofitting existing facilities and building new facilities.

The use of CIADMs during the COVID-19 response provided important insights on how to better invest in expanding manufacturing capacity and the need to develop a true capability. This led BARDA to launch the [Pharmaceutical Manufacturing in America \(PMIA\)](#) in 2020, which is a dedicated effort to strengthen domestic pharmaceutical manufacturing. During the COVID-19 pandemic, BARDA made critical investments to expand domestic manufacturing for pharmaceuticals and ancillary supplies, such as needles, syringes, glass vials, and various manufacturing components. BARDA also invested in domestic diagnostics manufacturing capacity expansion during the COVID-19 pandemic.

OBJECTIVE 2.2 KEY MILESTONES

- Establish a Biopharmaceutical Manufacturing Consortium of industry partners across the drug and vaccine manufacturing supply chain, including the manufacturers of required raw materials and consumables as well as suppliers of fill-finish services.
- Establish and maintain the capability to stand up commercial-scale vaccine production within 100 days of a declared public health emergency due to an agent with pandemic potential. This would yield at least 300 million vaccine regimens within 6-9 months of a declaration of a public health emergency by the Secretary of Health and Human Services.
- Establish and maintain a domestic capability to develop, manufacture, and obtain FDA Emergency Use Authorization and deploy over 100 million human pathogen-specific diagnostic tests, within 45 days (and every 30 days thereafter) of declaration of a public health emergency and access to the genome sequence.
- Expand domestic vaccine manufacturing capacity, leveraging innovative technologies.
- Work with antibiotic development and manufacturing companies to generate domestic production of critically needed antibacterial products and expand U.S.-based manufacturing capabilities.

WHAT'S NEW?



BARDA will build on these new partnerships to ensure the long-term sustainability of these critical capabilities, including leveraging new infrastructure lending authorities. BARDA's CIADM program is being re-envisioned as the National Biopharmaceutical Manufacturing Partnership (BioMaP). The next iteration of this program will promote manufacturing capabilities, not simply capacity, by ensuring facilities are staffed, trained, and actively manufacturing products that meet quality standards. BARDA will seek to expand capacity of the industrial base for consumables, raw materials, fill-finish, ancillary supplies, and diagnostics through novel partnerships with domestic manufacturers.



8 <https://www.medicalcountermeasures.gov/media/1138/mcmreviewfinalcover-508.pdf>

- Design and issue the first BARDA loan under a new infrastructure lending program.
- Demonstrate proof-of-concept for a vaccine candidate up to a Phase 1 clinical trial that is amenable to on-demand manufacturing and rapid distribution.

Domestic MCM Manufacturing Capacity Strengthening



MCM Manufacturing
Capacity Strengthening



Next Generation
Manufacturing Investments



MCM Industrial
Base Expansion

Figure 4: Domestic MCM Manufacturing Capacity Strengthening

Objective 2.3: Enhance and sustain response-ready support services

BARDA supports partners of all sizes and capabilities. BARDA often partners with innovative companies that have promising technologies but less commercial and regulatory experience than large companies. BARDA offers more than financial support to cultivate ideas from these companies. BARDA's Support Services provide technical assistance for these partners to accelerate promising technologies, which include:

- **Nonclinical Network:** Facilitate development and qualification of models in support of BARDA MCM development. Many licensed and approved MCMs have benefited from BARDA investments in the development of well-characterized animal models for vaccines and therapeutics developed under the Animal Rule.
- **Clinical Studies Network:** Provide comprehensive (Phases 1-4) clinical study services to help evaluate the safety, dosage, pharmacokinetics/pharmacodynamics, immunogenicity, and efficacy of MCM candidates. Provide long-term storage services for clinical and nonclinical biological specimens and investigational products for future assays. Provide a statistical and data coordinating center for harmonization across BARDA projects.
- **Regulatory and Quality Affairs:** Provide strategic support and opinions on quality and regulatory issues and sometimes serving as an Investigational New Drug (IND) sponsor to ensure safe and effective MCMs.
- **Fill Finish Manufacturing Network:** Address challenges to rapidly fill vials and finish packaging for MCMs on a population scale.
- **Pharmaceutical Countermeasures Infrastructure:** Collaborate with industry partners to ensure drug substance manufacturing, fill/finish, distribution, and administration capabilities are available to respond to public health emergencies.

WHAT'S NEW?



BARDA will examine dose-sparing approaches to increase the population that existing stockpile holdings could address. BARDA will support new regulatory approaches for threat-agnostic MCMs. BARDA will also work to ensure manufacturing capabilities are ready to respond during an emergency.



OBJECTIVE 2.3 KEY MILESTONES

- Establish well-characterized, product-agnostic, nonclinical/preclinical models for up to two emerging threats.
- Conduct nonclinical and clinical testing to determine if stockpiled vaccines can be effective with fewer or lower doses.
- Pressure test Pharmaceutical Manufacturing in America (PMIA)-supported domestic manufacturing capabilities at commercial scale and validate the process to ensure their readiness.
- Increase staffing and funding support for support services that reflects the expanding portfolio of products.

Objective 2.4: Leverage acquisition vehicles that enable rapid response

BARDA must be ready to rapidly establish or expand partnerships when a public health emergency occurs by having contracting vehicles pre-established. The first days of an emergency are critical, and delays in funding, resource availability, or contract awards costs lives.

During the COVID-19 response, BARDA leveraged existing BARDA Other Transaction Agreements (OTAs) as a flexible mechanism to invest in a portfolio of products that can evolve as needs change. Additionally, throughout the COVID-19 response, BARDA partnered closely with the Department of Defense (DoD) to leverage their existing OTA consortium to support critical contract awards to enter efficient and prudent partnerships. Flexibilities in these OTA partnerships were critical in enabling timely response.

OBJECTIVE 2.4 KEY MILESTONES

- Establish a new EZ-BAA contracting vehicle that enables both rapid initial funding and flexible rapid scaling for larger awards.
- Evaluate opportunities for BARDA to leverage an existing or establish a BARDA OTA consortium to create a coalition of potential partners ready for an emergency.
- To the maximum extent practicable, ensure all BARDA OTAs and FAR-based contracts include flexibilities to rapidly respond to known and unknown emerging infectious diseases.
- Increase the number of contracting officers and specialists within the BARDA organization and work to streamline the entire acquisition process within the Office of the Secretary of HHS.
- Conduct market research in the MCM space for viral families of pandemic potential to inform future acquisition mechanisms.

WHAT'S NEW?



BARDA will design and implement new acquisition vehicles that can be rapidly leveraged for research and development, manufacturing, and procurement for a public health emergency response. BARDA will also build on existing contractor staffing vehicles to rapidly acquire necessary staff to support emergency response, leveraging part-time services during non-response times.



Objective 2.5: Ensure BARDA's response posture accounts for the needs of all segments of the population

The COVID-19 pandemic highlighted the disparities in impact and provision of health care across racial, ethnic, and geographic lines. BARDA's prior investments in the emerging home use molecular testing space were quickly pivoted during the COVID-19 response to make high performance testing available in lower acuity and non-traditional settings, such as nursing homes, tribal health centers, and homes. BARDA must account for meaningful differences across populations that can impact health outcomes when preparing for and responding to public health emergencies. Geographic isolation, health workforce availability, and socioeconomic and environmental barriers are some of the key factors that should be considered in MCM investments. BARDA will continue working to ensure MCMs are developed that can be used for emergencies occurring across a range of populations and settings.

OBJECTIVE 2.5 KEY MILESTONES

- Develop proven technologies for detection that address needs of rural, frontier, tribal, and low-healthcare resourced communities – not just central commercial laboratories and large hospitals.
- Fund clinical study and trial recruitment that includes an appropriate balance of diverse backgrounds.
- Secure new digital clinical trial tools to target enrollment and expedite timelines (e.g., precision enrollment/stratify patients).
- Invest in a portfolio of at least five at-home testing technologies that will empower Americans, improve equitable access, and mitigate the impacts of future pandemics.
- Establish a new collaboration with the federal Office of Rural Health Policy (within the Health Resources and Services Administration) to identify countermeasure gaps in rural areas and fund products to mitigate gaps.

WHAT'S NEW?



BARDA will work with interagency partners to include considerations of diversity, equity, and inclusion in evaluations of MCM readiness, including how to ensure MCM access across a range of communities. BARDA's innovative, lifesaving products will be evaluated in the context of how they would be used in real-world circumstances to maximize product uptake and effectiveness in diverse populations.



Goal 3: Partnerships

Leverage mechanisms to foster flexible partnerships

In addition to supporting scientific innovation, BARDA supports innovative businesses with a proven track record by forming novel public-private partnerships. For each partnership, BARDA identifies the best potential business models, domestic and global partners, and the most advanced technology that can successfully deliver lifesaving MCMs in the event of a public health emergency.

BARDA's vision to grow and leverage these partnerships includes: (1) promoting adaptable partnership models, (2) sustaining current and establishing new partnerships, (3) identifying ways to promote long-term sustainability of supported products, and (4) expanding partnerships with socially and economically disadvantaged businesses.



Objective 3.1: Advance new, adaptable partnership models

New partnership models promise to create MCM development opportunities that have not been previously available. In 2021, [BARDA Ventures](#) was launched to stimulate innovation in product development using venture capital methods and practices, under unique authority granted in the 21st Century Cures Act.

OBJECTIVE 3.1 KEY MILESTONES

- BARDA Ventures will work with its nonprofit partner to establish a \$500 million global health security fund.
- BARDA Ventures will establish a model of shared scientific and business services to support and create emerging startups.
- BARDA Ventures will reinvest proceeds from successful returns on investment into additional companies, demonstrating the sustainability of the fund.

WHAT'S NEW?



BARDA will build out BARDA Ventures, led by its nonprofit partner, who will employ venture capital practices and methods to develop innovative MCMs for public health emergencies that also have commercial markets. The structure enables proceeds from these investments to be reinvested in the fund and, in turn, used to support development of other new technologies.

BARDA Ventures: *Transforming the Way Government Invests in MCMs of the Future*

- Agile investing towards building healthy companies of the future, not just today's technologies
- Led by an experienced venture capital investor with proven experience building health investment portfolios
- Equity and portfolio-based funding will generate global health impact and financial returns
- Built to scale: Ability to raise and operate a public-private \$500M Global Health Security Impact Fund
- Sustainable design enables the fund to invest & re-invest in transformative approaches to Pandemic Preparedness | CBRN Threats | Manufacturing of the Future

Figure 5: BARDA Ventures



Objective 3.2: Foster existing and establish new partnerships

While BARDA plays a critical role in developing and manufacturing MCMs, other PHEMCE agencies also have important roles. BARDA coordinates across U.S. Government departments and agencies to ensure harmonization of efforts. For example, as part of efforts to implement Executive Order 13887,⁹ BARDA will continue to work with partner agencies to develop and implement the National Influenza Vaccine Modernization Strategy (NIVMS), 2020-2030. The NIVMS outlines a vision for the U.S. influenza vaccine enterprise to be highly responsive, scalable, and more effective at reducing the public health impact of seasonal and pandemic influenza virus. This vision is supported by three strategic objectives:

- Strengthen and diversify development, manufacturing, and supply chain of influenza vaccines,
- Promote use of new technology to detect, prevent, and respond to influenza, and
- Increase access and coverage of influenza vaccines across all populations.

BARDA uses a comprehensive portfolio approach to develop and acquire a broad array of MCMs for pandemic influenza. This includes developing vaccines, therapeutics, diagnostics, and non-pharmaceutical countermeasures for influenza preparedness and building and sustaining facilities for their domestic manufacturing infrastructure.

OBJECTIVE 3.2 KEY MILESTONES

- Establish new interagency partnerships to release new solicitations and new partnership vehicles (e.g., cooperative research and development agreements and hybrid development/procurement vehicles) to develop MCMs, with added focus on emerging infectious diseases.
- Establish novel partnerships to collect real-time health data to improve operational intelligence enabling rapid development and deployment of MCMs.
- Establish a new 10-year accelerator partnership that brings together new global partners to advance promising antibacterial products.

WHAT'S NEW?



BARDA will establish new collaborations to support domestic manufacturing. BARDA will work with domestic and global partners to pursue opportunities to support MCM development, manufacturing, and operational intelligence to expand domestic and global access.

⁹ Executive Order 13887, Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health, <https://www.federalregister.gov/documents/2019/09/24/2019-20804/modernizing-influenza-vaccines-in-the-united-states-to-promote-national-security-and-public-health>



Objective 3.3: Enhance sustainability by supporting development and repurposing of products and technologies with commercial value

BARDA is acutely aware of the need to ensure the long-term sustainability of MCM investments. Some MCMs have potential to gain revenue in commercial markets, which can enhance sustainability and offset costs associated with the Federal Government stockpiling an MCM. However, market forces may not be enough to sustain innovators. For example, BARDA recently supported a novel antibiotic in obtaining FDA approval; however, the company failed to sustain a viable commercial market and entered bankruptcy. BARDA's commercial market risk exposure will increase as the portfolio diversifies and expands the coalition of partners. Commercial market dynamics must be evaluated to ensure access to MCMs that are vital to national security.

WHAT'S NEW?



BARDA will increase support to partners to evaluate commercial markets for MCMs, with a prioritization on companies launching their first commercial products, entering new markets, or facing reimbursement challenges. In addition, BARDA will seek longer-term commitments coordinated with the SNS, which would promote better value for public investment and reliability for private partners in their critical national security role.

OBJECTIVE 3.3 KEY MILESTONES

- Establish a new cross-organization commercial market-shaping team that evaluates and promotes commercialization and health care adoption.
- Work with commercial and governmental payers to mitigate reimbursement challenges in at least two economic sectors that impact BARDA-supported products and impair health security sustainability.
- Partner with SNS to establish new long-term contracts that can provide bridge support for products from BARDA's procurements under Project BioShield to the SNS.



Objective 3.4: Expand partnerships with socially and economically disadvantaged businesses

BARDA seeks to maintain a broad coalition of partners to develop MCMs that protect all segments of the population. In doing so, expanding outreach to innovators from historically disadvantaged groups is a critical need. The majority of BARDA's portfolio focuses on advanced research and development, and generally supports products that are in clinical trials (phases 1, 2, or 3). However, this limits the number of companies that have MCM candidates ready for BARDA investment and adds to the challenges for socially and economically disadvantaged businesses. While BARDA's investments are based on supporting the most promising scientific opportunities, BARDA works to ensure such disadvantaged companies have opportunities when their technologies are ready for investment.

In 2018, BARDA launched DRIVE to accelerate the development of innovative technologies and offer new opportunities for innovative companies, including small and minority-owned businesses. As part of the shift toward innovation and greater diversity of partners, BARDA's EZ-BAA – an acquisition vehicle for smaller contracts that have been awarded in as few as nine days – was designed to reduce barriers and improve opportunities for small and startup companies to develop promising technologies.

WHAT'S NEW?



BARDA will place greater focus on increasing diversity of all kinds in its portfolio and through market research and acquisition approaches. BARDA will leverage the innovative partnership models it has launched to provide greater emphasis on the inclusion of socially and economically disadvantaged businesses in their portfolio.

OBJECTIVE 3.4 KEY MILESTONES

- Increase number of EZ-BAA awards made to SBA 8(a) certified businesses, HubZone businesses, or woman- or service-disabled veteran-owned businesses.
- Increase number of awards under the BAA made to prime or sub-contractors who are SBA 8(a) certified businesses, HubZone businesses, or woman- or service-disabled veteran-owned businesses.
- Provide wraparound services (e.g., educational programming and access to various stakeholders that accelerate business and/or product development) to socially and economically disadvantaged startups with promising innovative technologies through BARDA's Accelerator Network.
- Establish processes to track TechWatch submissions to socially and economically disadvantaged businesses and develop engagement strategies for partnering with these prospective partners.



Goal 4: Workforce

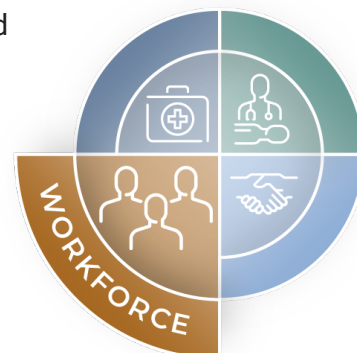
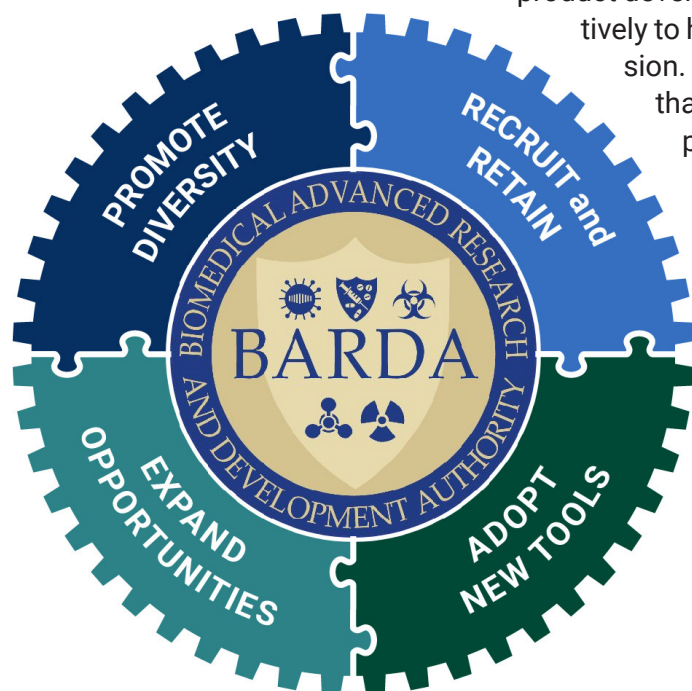
Build and support a world class workforce

Investing in the science that drives the development of innovative and next-generation MCMs is a critical component of BARDA's future success, and it is underpinned by its workforce and their available tools. BARDA must ensure that all personnel – both its federal workforce and support contractor workforce – feel empowered in advancing health security. BARDA will continue to foster a world class workforce by: (1) recruiting and retaining top talent, (2) promoting diversity across BARDA, including in leadership roles, (3) supporting career development and mentoring, and (4) providing staff the tools they need to perform effectively.

Objective 4.1: Recruit and retain leading experts across the BARDA enterprise

BARDA's track record of success in supporting the development and regulatory approval of MCMs is rooted in the dedication and scientific acumen of the individuals that constitute the BARDA organization. BARDA has been fortunate to bring together some of the country's leading experts in product development, contracting, partnerships, innovation, and program management. BARDA will continue to invest in its people, the studies and research they promote, and their professional growth.

People are the key to forging successful partnerships with MCM innovators. From its inception, BARDA has fostered a culture of innovation, teamwork, and collaboration between internal and external colleagues. BARDA leverages staff with decades of industry experience to provide scientific and drug product development expertise to partners, then works collaboratively to help turn ideas into products that help meet the mission. This culture of innovation and collaboration meant that there were existing relationships with industry partners to respond collaboratively, quickly, and successfully to COVID-19.



WHAT'S NEW?



BARDA will build on its interdisciplinary approach by augmenting project teams with experts to focus on key areas, such as health equity, commercialization, and response operations. BARDA will also invest in training and professional development, increase engagement at scientific conferences, and publish scientific findings.

Figure 6: Investing in BARDA's Workforce



OBJECTIVE 4.1 KEY MILESTONES

- Recruit and onboard 10 new subject matter experts in health equity, commercialization, and response operations.
- Expand recruiting efforts across the country, leveraging (where appropriate) remote work flexibility to increase the diversity of perspectives, grow the geographic recruitment area, and expand the scientific, programmatic, and contracting expertise within the organization.
- Ensure all Project Coordination Teams (PCTs) embed new subject matter experts in health equity, commercialization, and response operations into their product development teams.

Objective 4.2: Promote diversity across BARDA

The U.S. faces a substantial, longstanding disparity between the diversity in American communities and what is reflected in its science and engineering workforce; even with increasing numbers of women, Black and Hispanic STEM degree recipients since 2010, women and minorities remain underrepresented in the workforce.¹⁰ BARDA faces this same challenge, and seeks to achieve greater diversity in the organization that reflects the populations it serves.

BARDA's SPRINT (Science, Preparedness & Response, Innovations, and New Technologies) initiative was launched in 2021 to build a more inclusive workforce. This STEM outreach program aims to provide a centralized resource for students of all educational levels that highlights scientific topics BARDA encounters and encourages young minds to consider a path in science, science policy, and public service. In this endeavor, SPRINT aims to create a sustainable long-term pipeline for recruitment of diverse, bright, civic-minded, and talented future scientists.

WHAT'S NEW?



BARDA will grow relationships with faculty and alumni from historically black colleges and universities (HBCUs), Hispanic serving institutions, women's colleges, and tribal colleges and universities (TCUs) so that highly qualified graduates and post-doctoral scholars from these institutions may be aware of opportunities to work at BARDA. BARDA will also seek to recruit staff with expertise in health equity and social determinants of health, developing new initiatives to reduce health inequities and expand access to MCMs.

OBJECTIVE 4.2 KEY MILESTONES

- Continue to strengthen our commitment to ensuring diversity in our workforce through promoting training and career development opportunities for all members of BARDA's team.
- Engage historically Black colleges and universities (HBCUs), Hispanic serving institutions, women's colleges, and tribal colleges and universities (TCUs) by holding at least two recruitment events per year.
- Ensure geographical diversity of staff, leveraging remote work, to ensure rural health equities are considered to avoid an urban/suburban bias in product selection.
- Inspire next-generation scientists by initiating STEM programs with at least 10 racially and economically diverse schools through SPRINT.

¹⁰ Pew Research Center, April, 2021, "STEM Jobs See Uneven Progress in Increasing Gender, Racial and Ethnic Diversity" <https://www.pewresearch.org/science/2021/04/01/stem-jobs-see-uneven-progress-in-increasing-gender-racial-and-ethnic-diversity/> accessed on November 16, 2021.



Objective 4.3: Expand career development and mentorship opportunities

BARDA as a workplace is an excellent environment for developing the next generation of interdisciplinary scientific and public health professionals and leaders needed to accomplish the mission. Resources to foster such an environment include career development internships, career mobility opportunities, and leadership training. Additionally, BARDA has and will continue to participate in science, public health, and public administration fellowship programs such as the Presidential Management Fellowship (PMF), the Oak Ridge Institute for Science and Education (ORISE) fellowship, and the American Association for the Advancement of Science (AAAS) Science and Technology Policy Fellowship.

WHAT'S NEW?



BARDA will expand the number of roles for early- to mid-career professionals who can be mentored by senior professionals and grow into leadership roles. BARDA will recruit from relevant graduate and fellowship programs to identify promising scientists and professionals from a wide range of backgrounds who can join BARDA as pathway interns or mid-level staff.

OBJECTIVE 4.3 KEY MILESTONES

- Establish a recruitment network of at least five colleges and universities, prioritizing institutions with a strong track record of producing graduates from diverse backgrounds in fields such as science, engineering, public health, public administration, and business administration.
- Enhance upward mobility at BARDA through the greater use of career ladder positions, intra-divisional promotions, mentorship, training, and detail opportunities.
- Expand participation in federal fellowship programs (e.g., PMF, ORISE, AAAS) as a pipeline for talented staff and leadership development training programs.
- Establish staff exchange programs with other USG and international agencies to provide employees with experience across and foster relationships among all partnering agencies.

Objective 4.4: Adopt modern business, analytics, and communications tools to enhance efficiency

BARDA must have industry-leading business and analytical tools that optimize day-to-day operations to be adequately prepared for an emergency. The COVID-19 response dramatically scaled up operations beyond routine levels, highlighting the critical need for robust digital infrastructure and communication tools.

BARDA repurposed existing capabilities under BARDA Digital Resources (BDR) to build a real-time system during the pandemic to plan, track, and accept over 900 million COVID-19 vaccine doses. BARDA must learn from this experience and build on the capabilities successfully created to support the COVID-19 response to ensure there are agile systems capable of supporting future public health emergency response, as well as meet the needs of daily operations. BARDA also increased availability of information about MCMs to the public, including expanding its presence on social media and publishing interactive timelines, portfolios, and explanatory articles.



OBJECTIVE 4.4 KEY MILESTONES

- Award a new 10-year Enterprise Information Technology Support (EITS) partnership to ensure BARDA data, information, and communication teams have the resources and tools that can scale to address future emerging threats.
- Track all partner interactions systematically, through intuitive interfaces to streamline communication and enhance productivity, including 90% of funding proposal submissions and 100% of funding proposal reviews routed through automated systems. This will cut the administrative burden on external partners and staff, facilitating speed and accuracy of responses to requests for information.
- Recognition as a top Federal organization for technology integration in MCM development and support.

WHAT'S NEW?



BARDA will make a 10-year commitment to innovate and scale new communications, data, and technology applications across the portfolio. BARDA will implement contracting software to provide staff with cutting-edge tools and retain strong contracting professional candidates. BARDA will also invest in technology, data management and architecture, business process automation, and accurate analytics to strengthen response posture. In close collaboration with HHS Information Technology and Data leadership, BARDA will provide teams with the tools they need while ensuring systems meet Federal safety and security standards.

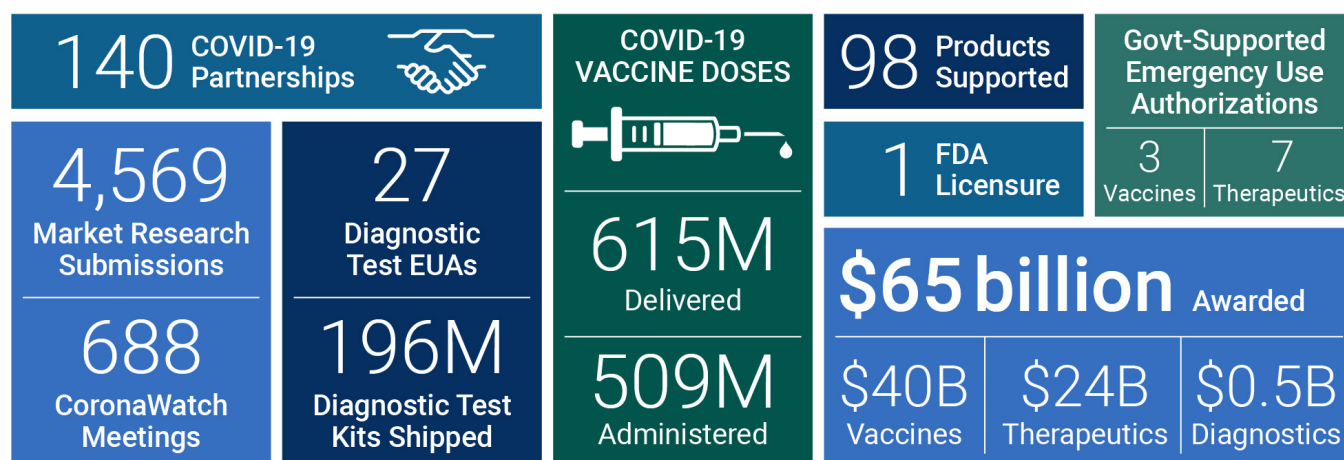


Appendix 1

BARDA's Contributions to the COVID-19 Pandemic Response

COVID-19 Accomplishments

The COVID-19 pandemic represents one of the greatest threats to public health the world has faced in more than 100 years. Public-private partnerships to develop and produce MCMs have been critical in responding to the pandemic. BARDA has and continues to play a critical role in the COVID-19 response. BARDA has coordinated activities closely within the Department of Health and Human Services (HHS) and Department of Defense (DoD) agencies to ensure a whole-of-government approach.



Metrics as of 12/31/2021

Figure 7: BARDA's Rapid Response to the COVID-19 Pandemic Laid Foundations for Successes

Early in the COVID-19 pandemic response, BARDA assessed its portfolio of existing partners for technologies that could support development of MCMs against COVID-19, and quickly pivoted to initiate development of COVID-19 products. Less than one month after the SARS-CoV-2 sequence was shared, BARDA leveraged existing public-private partnerships that included options to support pandemic preparedness and response activities. BARDA also pivoted rapidly to develop an array of MCMs to address COVID-19. These initial investments were made with annual appropriations, prior to the availability of supplemental funding.

On January 30, 2020, ASPR/BARDA hosted an industry stakeholder engagement session, with broad participation across relevant U.S. Government agencies, to communicate MCM needs and challenges with developers. BARDA established a COVID-19 Market Research Portal ("CoronaWatch") to facilitate a centralized, all-of-government portal for submission and review of potential MCMs to diagnose, treat, or prevent COVID-19, leveraging BARDA's TechWatch program. Submissions were reviewed by subject-matter experts from across the USG, and promising candidates were selected for further discussions with interagency partners. By the end of 2021, BARDA received 4,569 submissions to the CoronaWatch portal and held 688 meetings with developers.

In March 2020, BARDA received supplemental funding that enabled accelerated efforts to rapidly develop and gain Emergency Use Authorizations (EUAs) for MCMs. These actions resulted in EUAs for multiple

vaccines, therapeutics, and diagnostics, and production of hundreds of millions of doses of COVID-19 vaccines, millions of doses of monoclonal antibody therapeutics, and over 182 million diagnostic tests. While vaccine candidates were still under development, BARDA simultaneously initiated critical work to dramatically expand domestic manufacturing capacity (including for ancillary supplies such as needles and syringes) and secure supply chains to ensure life-saving vaccines would be available for mass vaccination. Details about BARDA's COVID-19 MCM portfolio can be found on the BARDA website.¹¹

Given the volume and urgency of MCM development, manufacturing, and procurement needs for the COVID-19 response, BARDA partnered with DoD through Operation Warp Speed and subsequently the Countermeasures Acceleration Group to execute many of the investments described below.

The success in development, regulatory approval, and production of COVID-19 diagnostics, therapeutics, and vaccines is rooted in the previous 15 years of BARDA investments in MCM preparedness. These programs allowed BARDA to immediately launch and execute an MCM development plan when the pandemic began. Subsequent acceleration efforts supported manufacturing expansion and EUA of vaccines, therapeutics, and diagnostics in record time. Throughout the COVID-19 response process, BARDA identified potential risks that have been addressed (e.g. limited supply of needles and syringes) or are subject of actions under this strategic plan.

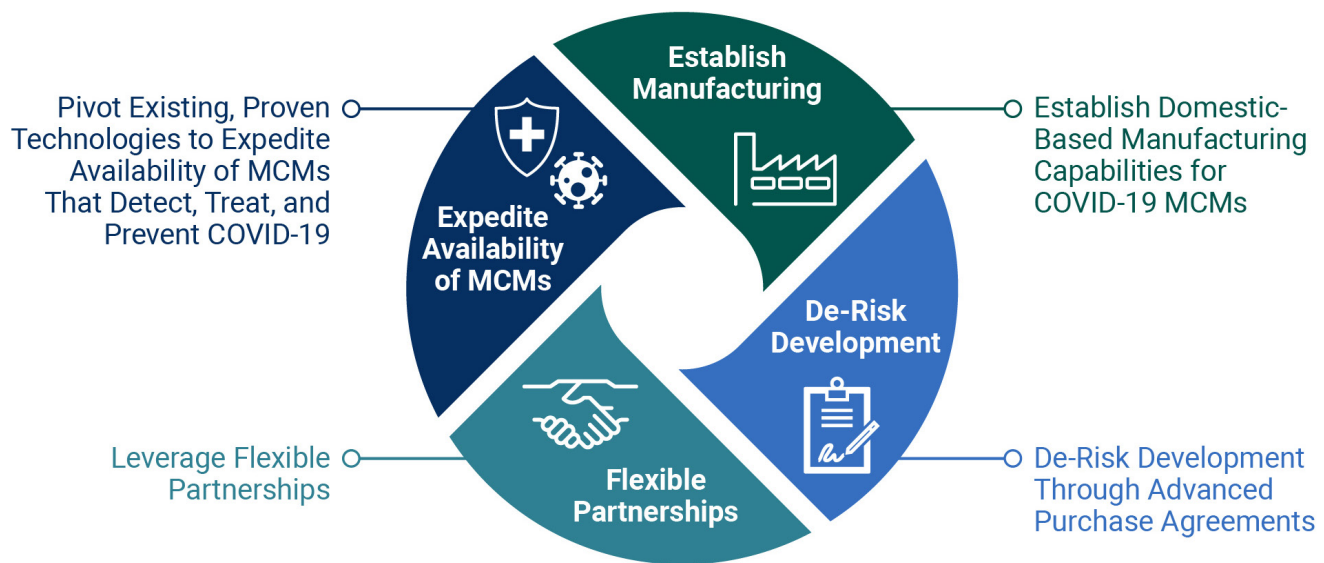


Figure 8: COVID-19 Medical Countermeasure Development Strategy

BARDA COVID-19 Vaccine Investments

BARDA invested in a portfolio of vaccine candidates that showed potential to be: (1) safe and effective, (2) rapidly developed for addressing the pandemic in a relevant timeframe, and (3) in parallel with clinical trials, manufactured at a scale sufficient to meaningfully contribute to a national vaccination campaign. BARDA supported advanced development of five vaccine candidates and an advanced purchase agreement for one candidate that de-risked the development of the candidate. Less than 12 months from receiving COVID-19 supplemental funds, three vaccine candidates received EUA from the FDA. Previous investments made by BARDA on three vaccine platforms (Ad26-vectors, recombinant baculovirus ex-

¹¹ <https://www.medicalcountermeasures.gov/app/barda/coronavirus/COVID19.aspx>

pression systems, and mRNA) facilitated the rapid development, manufacturing, and scale-up of several candidates. Investments in multiple candidates served as the basis for Operation Warp Speed, and subsequently the Countermeasures Acceleration Group, portfolio.

BARDA also secured manufacturing scale-out and scale-up, fill/finish capacity, and ancillary supplies (e.g., needles and syringes). These capabilities included substantial investments in U.S.-based manufacturing. BARDA product development contracts funded and supported in-house technical assistance across all phases of product development and manufacturing for the vaccine candidates, including phase 1, 2, and 3 clinical trials; manufacturing; validation and scale-up; quality oversight; nonclinical support; and regulatory support. BARDA is also supporting novel vaccine approaches and platforms to accelerate vaccine availability, delivery, and administration. These included alternative vaccine administration approaches for addressing a potential shortage of needles and syringes as well as needleless vaccine administration technologies.

BARDA COVID-19 Therapeutic Investments

Addressing the COVID-19 pandemic requires developing and procuring therapeutics for individuals across the continuum of disease, from mild infections to the severely ill. BARDA invested COVID-19 supplemental funds to accelerate the clinical development and manufacturing scale-up of therapeutic candidates most likely to have a broad public health impact. BARDA supported screening existing monoclonal antibodies and small molecule compounds with existing clinical or preclinical data for activity against SARS-CoV-2. An existing partnership was expanded by BARDA to develop new targeted monoclonal antibodies using a proven technology that was licensed for another indication. In addition, BARDA supported the collection, distribution, and EUA of COVID-19 convalescent plasma, which was used to treat approximately 400,000 patients.

BARDA COVID-19 Diagnostic Investments

Diagnostics are a crucial tool to aid in the diagnosis and inform management and treatment of COVID-19 patients, which can assist in reducing the spread of this deadly disease. BARDA supported multiple assays for SARS-CoV-2 infection that spanned over 40 diagnostic products. From May to June 2020, approximately 40% of the COVID-19 diagnostics available for Americans were the result of BARDA investments. These included high-throughput devices in commercial clinical labs and hospitals, point-of-care tests for use in provider offices and limited testing resource settings (such as nursing homes), and over-the-counter tests for home use. Tests supported also included multiplex molecular diagnostic tests that detect SARS-CoV-2, in addition to influenza A and B viruses, and, in some cases, respiratory syncytial virus (RSV). BARDA's first supported diagnostic was authorized for emergency use in March 2020. BARDA also supported the development of diagnostics to distinguish specific SARS-CoV-2 variants when needed to inform therapeutic usage. BARDA also collaborated with NIH, providing both financial support and subject-matter expertise to facilitate rapid launch of the RAD-X program.

In parallel, BARDA invested in rapidly deployable capabilities that augment current diagnostic technologies, leveraging the physiological, host biomarkers, and vital sign data from patients. These included exploring the capability of non-invasive, wearable physiological sensors, remote monitors, and telemedicine tools to empower individuals and health care providers to better inform on infection status (including those that may be asymptomatic or pre-symptomatic) or infection severity. Such technologies could aid in identifying at-risk individuals, reducing further transmission by providing early indication of infection and monitoring mildly ill patients that may be progressing to more severe illness.

In addition, BARDA supported technologies that included electronic health records – integrated algorithms, apps, and blood biomarker-based in vitro diagnostics. These efforts empowered health care pro-

viders in the emergency department and hospital. Such technologies could provide early information on health deterioration to aid health care providers in management of patients to improve patient outcomes and allocate resources.

BARDA also partnered with DoD to make substantial investments in domestic diagnostics manufacturing, which will increase diagnostic test production capacity output from 18 million to 72 million tests per month in 2022 and will help ensure domestic supply.

BARDA's COVID-19 response continues with new countermeasures in development, and BARDA anticipates incorporating current and future activities to address SARS CoV-2 as a durable facet of its mission. In addition, there is an opportunity to expand indications beyond COVID-19 and demonstrate utility of some of the host-based diagnostic technologies funded under rapidly deployable capabilities against a broader range of illnesses (e.g., respiratory infections). Host-based technologies should be inherently pathogen-agnostic. Therefore, with future research and development, BARDA can demonstrate greater value to support the nation's pandemic preparedness posture.

Appendix 2

Overview of Key Legislation



ASPR and BARDA's legal authorities for preparing and responding to public health emergencies are based in the Public Health Service Act (42 USC 247d). The relevant impact for BARDA's mission from various amendments to the act are highlighted below.

- **Project BioShield Act of 2004:** Project BioShield provided incentives to industry to develop MCMs for which traditional markets were not sufficient to promote private investment. This act also established a fund that may be used to procure MCMs for the SNS, prior to licensure, if they may be made available under an EUA during a public health emergency.
- **Public Readiness and Emergency Preparedness (PREP) Act of 2005:** The PREP Act authorizes the HHS Secretary to issue a declaration that provides some immunity from liability to individuals and organizations involved in the development and use of certain FDA-regulated MCMs. It does not exempt liability for willful misconduct.
- **Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA):** PAHPA established the ASPR organization, including BARDA as a part of ASPR. The act also provided new authorities for advanced development and acquisitions of MCMs.
- **Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA) of 2013:** PAHPRA reauthorized BARDA and the funds for procurement of MCMs through 2018. PAHPRA also increased the flexibility of Project BioShield to support advanced research and development of potential MCMs.
- **21st Century Cures Act of 2016:** This act clarified BARDA contracting authorities. In addition, it provided to BARDA the authorities related to the use venture capital methods and practices.
- **Pandemic and All Hazards Preparedness and Advancing Innovation Act (PAHPAIA) of 2019:** PAHPAIA reauthorized BARDA and the funds for procurement of MCMs through 2023.

